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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/850,353	05/02/1997	YESOOK KIM	PC9563JTJ	4835

7590 06/15/2005

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EXAMINER

WHITE, EVERETT NMN

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/15/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

08/850,353

Applicant(s)

KIM, YESOOK

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 25 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 3 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/25/2005</u> | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on March 25, 2005 has been entered.
2. The amendment filed March 25, 2005 has been received, entered and carefully considered. The amendment affects the instant application accordingly:
  - (A) Claims 1 and 2 have been canceled;
  - (B) Comments regarding Office Action have been provided drawn to:
    - (I) 102(a) rejection, which has been maintained for the reasons of record.
3. Claim 3 is pending in the case.
4. The text of those sections of Title 35, U. S. Code not included in this action can be found in a prior Office action.

### ***Claim Rejections - 35 USC § 112***

5. Claim 3 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 lacks clarity, which renders the claim indefinite because the claim is directed to a method of determining a useful salt, but does not set forth in the claim what the salt is useful for. The terms "composition of matter" and "medicinal compound" are noted, but do not clarify the claimed invention since a composition has not been identified as being the claimed invention. Claim 3 also has not been established as a process for preparing a particular composition or as a method of treating a particular condition wherein the composition is administered to an individual.

Claim 3 is further indefinite because the claim describes steps that involve accomplishing a task, but does not clearly describes the task that is achieved. The claim recites a "medicinal compound" and "therapeutic efficacy", but does not specify the medicinal compound or what condition is being treated.

6. Applicant's arguments with respect to claim 3 have been considered but are moot in view of the new ground(s) of rejection.

***Claim Rejections - 35 USC § 102***

7. Claim 3 is rejected under 35 U.S.C. 102(a) as being anticipated by Chiese et al (US Patent No. 5,773,029) for the reasons disclosed on pages 3-5 of the Office Action mailed November 20, 2003.

8. Applicant's arguments filed March 25, 2005 have been fully considered but they are not persuasive. Applicants argue that at least steps (a), (b), (c) and (f) of the instantly claimed method was not found in the Chiesi et al patent. Specifically, these steps involve (a) determining a quantity of said medicinal compound required for therapeutic efficacy; (b) choosing a maximum total dose in which to administer said quantity of medicinal compound; (c) calculating the minimum required solubility of a salt of said compound necessary to formulate said maximum total dose; (f) selecting, as said useful salt, a salt from said series having an equilibrium solubility in cyclodextrin sufficient to permit making a total dose equal to or less than said maximum total dose. This argument is not persuasive because the Chiesi et al patent does set forth various acidic drugs, which are well known in the art, including their therapeutic efficacy or the dose that may be administered to a patient to treat a particular condition. See column 3, 2<sup>nd</sup> paragraph for a list of acidic drugs that include oxicans, hypoglycemic sulfonylureas, bezothiadiazine diuretics, barbituric acids, arylacetic and arypropionic anti-inflammatory acids. Also see Examples 1-11 and Tables 1-6, which set forth well known acidic drugs, salts thereof, and complexes thereof with cyclodextrins. The solubility is calculated in some of the Examples and Tables of the Chiesi et al patent (e.g., see examples 9-11 and Tables 1-6). The Chiesi et al patent does set forth information, which expressly or inherently anticipate the instantly claimed invention.

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Accordingly, the rejection of Claim 3 under 35 U.S.C. 102(a) as being anticipated by the Chiese et al patent is maintained for the reasons of record.

**Summary**

9. Claim 3, the only pending claim of record, is rejected.

**Examiner's Telephone Number, Fax Number, and Other Information**


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.

  
E.White

  
James O. Wilson  
Supervisory Primary Examiner  
Technology Center 1600